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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,734	03/30/2001	Artur Pedyczak	API-02-07-US	5460

7590  
Patrick J. Halloran  
Aventis Pasteur  
Discovery Drive  
Swiftwater, PA 18370

09/01/2005

EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/821,734

Applicant(s)

PEDYCZAK ET AL.

Examiner

Sheela J. Huff

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 6/7/04 and 4/29/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-9, 24, 25, 27, 28, 30, 31, 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 and 34 is/are allowed.
- 6) ☒ Claim(s) 6, 8, 9, 24, 25, 27, 28, 30, 31 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/14/03</u> . | 6) <input checked="" type="checkbox"/> Other: <u>EXHIBIT A</u> .                        |

## **DETAILED ACTION**

### ***Response to Amendment***

The amendments filed on 6/7/04 and 4/29/05 have been considered. Applicant's arguments are deemed to be persuasive.

The rejection of claims 26-28 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's arguments.

Claims 6-9, 24-25, 27-28, 30-31, 33-34 are pending.

### ***Information Disclosure Statement***

The documents submitted 11/14/03 has been fully considered and an initialed copy of the PTO-1449 is enclosed.

### ***Declaration***

The declaration remains defective for the reasons of record. Applicant indicates that a new declaration will be filed shortly.

### ***Claim Rejections - 35 USC § 112***

Claims 6 and 30-31 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid sequence encoding SEQ ID NO. 12-17, does not reasonably provide enablement for a nucleic acid

Art Unit: 1643

sequence encoding X-X1-X-X-X-X-X-X2 or analogs or sequences with substantial sequence homology thereto. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The reasons for this rejection are of record in the paper mailed 1/5/04.

Applicant argues that the claims have been amended to remove the non-enabled subject matter.

Claim 6 (a) and 30-31 still reads on conservative substitutions and as defined by applicant in the specification on page 7 "analogs" include peptides with conservative substitutions.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

Claims 6, 8-9, 24-25, 27-28, 30-31, 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims read on a nucleic acid sequence that is complementary to SEQ ID NO. 12-17 or nucleic acid sequences that hybridize to SEQ ID NO. 12-17 encoding PSMA derived peptide.

Sequence that are complementary to or hybridize to SEQ ID NO. 12-17 are the antisense strand and the antisense strand usually does not encode any peptide and certainly does not encode the same sequence that the sense strand encodes.

Applicant has not provided any examples to show that the antisense strand can encode any peptide or even encode the PSMA derived peptides. In view of the fact that the antisense strand does not encode a peptide and in view of the lack of examples to that the antisense strand encodes a peptide, it is the Examiner's position that the undue experimentation would be required by one skilled in the art to make the instant invention.

Claims 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to nucleic acid sequences that encode Seq ID NO. 12-17 and additionally have 1-10 amino acids on either end of said sequence. These additional amino acids read on any amino acid and applicant has not adequately described the additional amino acids and that he has possession of such sequences. The specification as filed does not provide adequate written description support for such sequences. Adequate written description requires more than a mere statement that it is part of the invention. The sequence itself is required. See Fiers v. Revel, 25

Art Unit: 1643

USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.,  
18 USPQ2d 1016.

Therefore, only SEQ ID No. 12-17 meet the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed. (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. (See Vas-Cath at page 1116.).

Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 8-9, 24-25, 27-28, 30-31, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Harrison et al 5827812.

This reference discloses Seq ID NO. 13 where nucleotides 216-242 of SEQ ID NO. 13 have 77.8% similarity to SEQ ID NO. 17 (see attached Exhibit A). This reference also discloses vectors and host cells (col. 4, lines 9-17). Because the instant

Art Unit: 1643

set of claims is drawn to an isolated nucleic acid sequence that encodes isolated PSMA "derived" peptide wherein the amino acid sequence is shorter than that of the isolated PSMA "derived" peptide, it is the Examiner's position that SEQ ID NO. 13 of the reference contains nucleotides 216-242 that are "derived" from SEQ ID NO. 17. Also because there are two shorter sequences of 4 contiguous nucleotides that are part of 216-242 these are "shorter than" Seq ID NO. 17.

***Allowable Subject Matter***

Claims 7 and 34 are allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesdays and Thursdays from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sheela J Huff  
Primary Examiner  
Art Unit 1643

sjh



EXHIBIT A

US-08-308-95219

Query Match: 64.4% Score 17.4; DB 2; Length 612;  
Best Local Similarity 77.8%; Pred. No. 53;  
Matches 21; Conservative 0; Mismatches 6; Indels 0; Gaps 0;

QY 1 GCTCTGTTTGATATGAAAGCAAGTG 27  
DB 216 GTTCTGCTGATGTAAGCAAGG 242

RESULT 8  
US-08-308-952-13  
; Sequence 13; Application US/08308952  
; Patent No. 5837812  
; GENERAL INFORMATION:  
; APPLICANT: Harrison, Leonard  
; APPLICANT: Honeyman, Margot  
; APPLICANT: Cram, David  
; APPLICANT: Dealpurua, Henry  
; TITLE OF INVENTION: A METHOD FOR THE DIAGNOSIS AND TREATMENT  
; TITLE OF INVENTION: OF GLUTAMIC ACID DECARBOXYLASE AUTOANTIGEN  
; NUMBER OF SEQUENCES: 25  
; CORRESPONDENCE ADDRESS:  
; ADDRESSEE: Scully, Scott, Murphy & Presser  
; STREET: 400 Garden City Plaza  
; CITY: Garden City  
; STATE: New York  
; COUNTRY: U.S.A.  
; ZIP: 11530  
; COMPUTER READABLE FORM:  
; MEDIUM TYPE: Floppy disk  
; COMPUTER: IBM PC compatible  
; OPERATING SYSTEM: PC-DOS/MS-DOS  
; SOFTWARE: Patent in Release #1.0, Version #1.25  
; CURRENT APPLICATION DATA:  
; APPLICATION NUMBER: US/08/308,952  
; FILING DATE:  
; CLASSIFICATION: 435  
; PRIOR APPLICATION DATA:  
; APPLICATION NUMBER: 839,805  
; FILING DATE: 21-FEB-1992  
; ATTORNEY/AGENT INFORMATION:  
; NAME: Digiglio, Frank S.  
; REGISTRATION NUMBER: 31,346  
; TELECOMMUNICATION INFORMATION:  
; TELEPHONE: (516) 742-4343  
; TELEFAX: (516) 742-4366  
; TELEX: 230 901 SANS UR  
; INFORMATION FOR SEQ ID NO: 13:  
; SEQUENCE CHARACTERISTICS:  
; LENGTH: 612 base pairs  
; TYPE: nucleic acid  
; STRANDEDNESS: single  
; TOPOLOGY: linear  
; MOLECULE TYPE: cDNA to mRNA  
US-08-308-952-13

Query Match: 64.4% Score 17.4; DB 2; Length 612;  
Best Local Similarity 77.8%; Pred. No. 53;  
Matches 21; Conservative 0; Mismatches 6; Indels 0; Gaps 0;

QY 1 GCTCTGTTTGATATGAAAGCAAGTG 27  
DB 216 GTTCTGCTGATGTAAGCAAGG 242

RESULT 9  
US-09-124-141-12  
; Sequence 12; Application US/09124141  
; Patent No. 6211352  
; GENERAL INFORMATION:

APPLICANT: Harrison, Leonard  
APPLICANT: Honeyman, Margot  
APPLICANT: Cram, David  
APPLICANT: Dealpurua, Henry  
TITLE OF INVENTION: A METHOD FOR THE DIAGNOSIS AND TREATMENT OF GLUTAMIC  
FILE REFERENCE: PHILLIPS, Ormonde & Fitzpatrick  
CURRENT APPLICATION NUMBER: US/09/124,141  
CURRENT FILING DATE: 1998-07-29  
EARLIER APPLICATION NUMBER: 08/308,952  
EARLIER FILING DATE: 1994-09-20  
EARLIER APPLICATION NUMBER: 07/839,805  
EARLIER FILING DATE: 1992-02-21  
NUMBER OF SEQ ID NOS: 34  
SOFTWARE: Patent in Ver. 2.1  
SEQ ID NO 12  
LENGTH: 612  
TYPE: DNA  
ORGANISM: Unknown Organism  
FEATURE:  
OTHER INFORMATION: Description of Unknown Organism: C-terminal  
OTHER INFORMATION: Fragment of Mouse Brain GAD.(HBGAD56)  
FEATURE:  
NAME/KEY: CDS  
LOCATION: (1)...(609)  
US-09-124-141-12

Query Match: 64.4% Score 17.4; DB 4; Length 612;  
Best Local Similarity 77.8%; Pred. No. 53;  
Matches 21; Conservative 0; Mismatches 6; Indels 0; Gaps 0;

QY 1 GCTCTGTTTGATATGAAAGCAAGTG 27  
DB 216 GTTCTGCTGATGTAAGCAAGG 242

RESULT 10  
US-09-124-141-20  
; Sequence 20; Application US/09124141  
; Patent No. 6211352  
; GENERAL INFORMATION:  
; APPLICANT: Harrison, Leonard  
; APPLICANT: Honeyman, Margot  
; APPLICANT: Cram, David  
; APPLICANT: Dealpurua, Henry  
; TITLE OF INVENTION: A METHOD FOR THE DIAGNOSIS AND TREATMENT OF GLUTAMIC  
; TITLE OF INVENTION: ACID DECARBOXYLASE AUTOANTIGEN ASSOCIATED DISEASES  
; FILE REFERENCE: PHILLIPS, Ormonde & Fitzpatrick  
; CURRENT APPLICATION NUMBER: US/09/124,141  
; CURRENT FILING DATE: 1998-07-29  
; EARLIER APPLICATION NUMBER: 08/308,952  
; EARLIER FILING DATE: 1994-09-20  
; EARLIER APPLICATION NUMBER: 07/839,805  
; EARLIER FILING DATE: 1992-02-21  
; NUMBER OF SEQ ID NOS: 34  
; SOFTWARE: Patent in Ver. 2.1  
; SEQ ID NO 20  
; LENGTH: 612  
; TYPE: DNA  
; ORGANISM: Unknown Organism  
; FEATURE:  
; OTHER INFORMATION: Description of Unknown Organism: C-terminal  
; OTHER INFORMATION: Fragment of Human Brain GAD (HBGAD65)  
; FEATURE:  
; NAME/KEY: CDS  
; LOCATION: (1)...(609)  
US-09-124-141-20

Query Match: 64.4% Score 17.4; DB 4; Length 612;  
Best Local Similarity 77.8%; Pred. No. 53;  
Matches 21; Conservative 0; Mismatches 6; Indels 0; Gaps 0;

QY 1 GCTCTGTTTGATATGAAAGCAAGTG 27